INNOVATIVE SUPPORT FOR PATIENTS WITH SARS COV-2 INFECTIONS REGISTRY (INSPIRE)

Rush University

University of Washington

Yale University

on behalf of the INSPIRE consortium

Disclosure

- Harlan M. Krumholz is co-founder of Hugo Health; Wade Schulz is a consultant to Hugo Health; Dave Hutten is the Product Lead at Hugo Health; Deb Chromik is a consultant to Hugo Health.

Participants

Speakers:

Harlan M. Krumholz MD. Harold H. Hines Jr. Professor of Medicine), Yale University

Bala Hota MD. Professor of Internal Medicine (Infectious Disease), Rush University

Graham Nichol, MD. Medic One Foundation Chair for Pre-hospital Emergency Care, UW

Other Panelists:

Jacqueline Rollin, Administrative Fellow, Rush University Medical Center

Wade Schulz, MD, PhD. Assistant Professor of Laboratory Medicine

Matthew J. Thompson, MB, ChB, DPhil, Helen D. Cohen Professorship in Family Medicine, UW

Deb R. Chromik, Participant Experience, Hugo Health

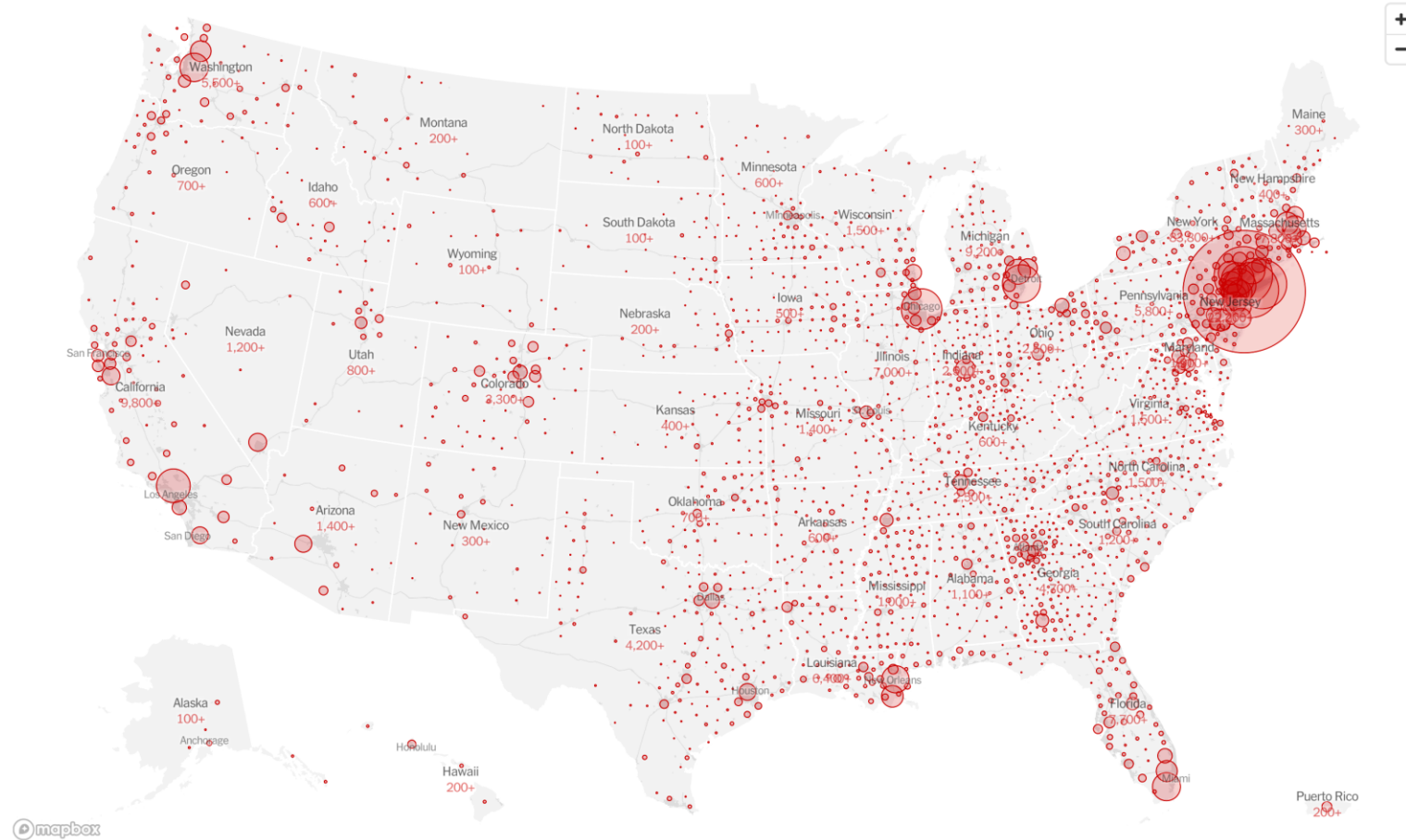**Dave Hutton**, Product Lead, Hugo Health
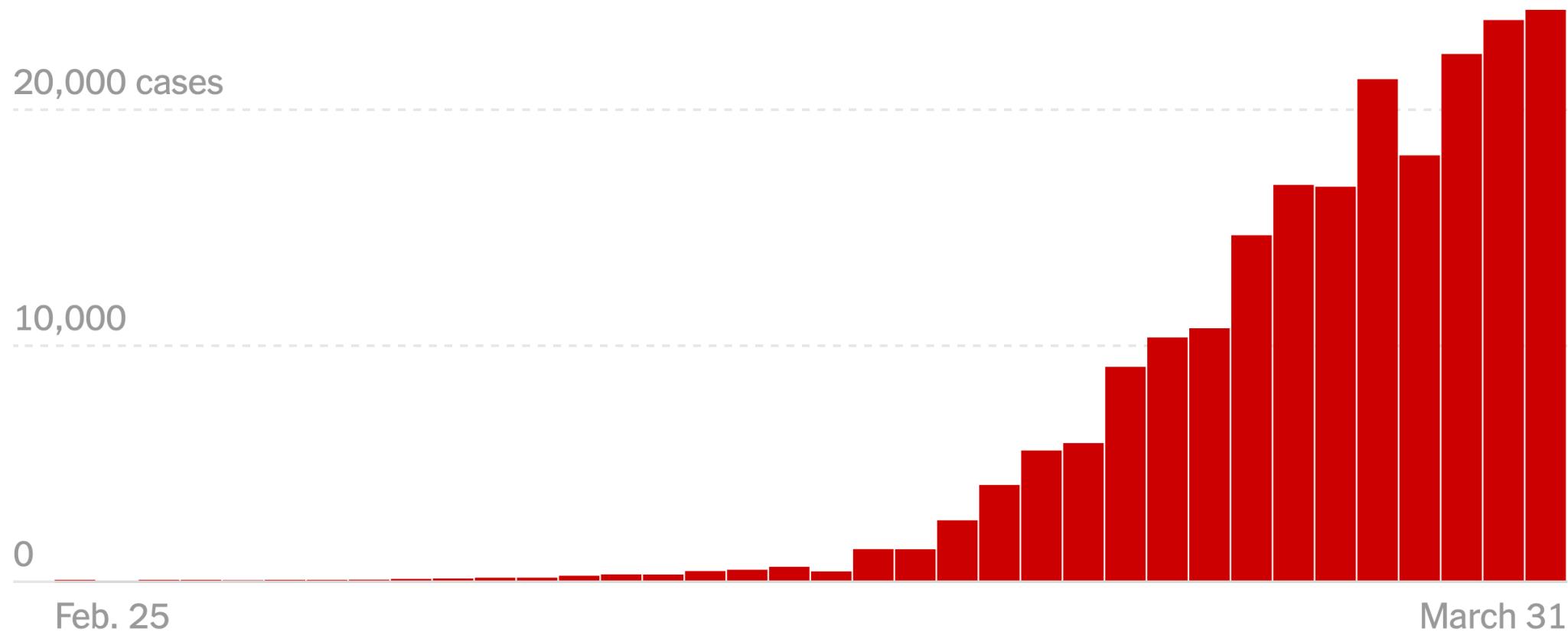
Confirmed cases in the United States

Total cases | Deaths

10 cases • ○ ◯ 5,000 cases

Zoom and hover over map for more detail

Washington
5,600+

Maine
300+

Montana
200+

North Dakota
100+

Minnesota
600+

New Hampshire
400+

Oregon
700+

Idaho
600+

South Dakota
100+

Wisconsin
1,500+

New York
Massachusetts

Michigan
9,200+

Wyoming
100+

Iowa
500+

Nebraska
200+

Illinois
7,000+

Indiana
900+

Ohio
2,800+

Pennsylvania
5,800+

New Jersey

Maryland

Nevada
1,200+

Utah
800+

Colorado
2,300+

Kansas
400+

Missouri
1,400+

Kentucky
600+

Virginia
1,500+

San Francisco

California
9,800+

Los Angeles

San Diego

Arizona
1,400+

New Mexico
300+

Oklahoma

Arkansas
600+

Tennessee

North Carolina
1,500+

South Carolina

Mississippi
1,000+

Alabama
1,100+

Georgia
4,200+

Texas
4,200+

Dallas

Louisiana
4,000+

New Orleans

Houston

Florida

Alaska
100+

Anchorage

Honolulu

Hawaii
200+

Miami

Puerto Rico
200+

New reported cases by day in the United States

The Need

EDITORIAL

Ten Weeks to Crush the Curve

Harvey V. Fineberg, M.D., Ph.D.

6. **Learn while doing through real-time, fundamental research.** Clinical care would be vastly improved by effective antiviral treatment, and every plausible avenue should be investigated. We did it with HIV; now, we need to do it faster with SARS-CoV-2. Clinicians need better predictors of which patient's condition is prone to deteriorate rapidly or who may go on to die. Decisions to shape the public health response and to restart the economy should be guided by science.

Defining the Epidemiology of Covid-19 — Studies Needed

Marc Lipsitch, D.Phil., David L. Swerdlow, M.D., and Lyn Finelli, Dr.P.H.

The epidemic of 2019 novel coronavirus (now called SARS-CoV-2, causing the disease Covid-19) has expanded from Wuhan throughout China and is being exported to a growing number of countries, some of which have seen onward transmission. Early efforts have focused on describing the clinical course, counting severe cases, and treating the sick. Experience with the Middle East respiratory syndrome (MERS), pandemic influenza, and other outbreaks has shown that as an epidemic evolves, we face an urgent need to expand public health activities in order to elucidate the epidemiology of the novel virus and characterize its potential im-

And how can we identify groups most likely to have poor outcomes so that we can focus prevention and treatment efforts?

The table lists approaches to answering these questions, each of which has shown success in prior disease outbreaks, especially MERS and pandemic H1N1 influenza.[1]

Counting the number of cases, including mild cases, is necessary to calibrate the epidemic response. Conventional wisdom dictates that the sickest people seek care and undergo testing; early in an epidemic, case fatality and hospitalization ratios are often used to assess impact. These measures should be interpreted

taining surveillance when cases become too numerous to count. This approach, which can be adapted to Covid-19, involves using existing surveillance systems or designing surveys to ascertain each week the number of persons with a highly sensitive but nonspecific syndrome (for example, acute respiratory infection) and testing a subset of these persons for the novel coronavirus. The product of the incidence of acute respiratory infection (for example) and the percent testing positive provides an estimate of the burden of cases in a given jurisdiction.[1] Now is the time to put in place the infrastructure to accomplish such surveillance.

Types of Evidence Needed for Controlling an Epidemic.

Evidence Needed	Study Type
No. of cases, including milder ones	Syndromic surveillance plus targeted viral testing
Risk factors and timing of transmission	Household studies
Severity and attack rate	Community studies
Severity "pyramid"	Integration of multiple sources and data types
Risk factors for infection and severe outcomes, including death	Case–control studies
Infectiousness timing and intensity	Viral shedding studies

Focus

- Risk-stratification of patients
- Platform to rapidly test diagnosis, therapeutics and back to work strategies - and support life sciences

Key Outcomes

- Hospitalizations, acute care visits, symptom burden, health status, death

Need…

- Address the mechanics… how?

Properties of the solution

- Rapid deployment
- Timely, fit-for-use data
- Participant-centric
- Trustworthy
- Low-burden on clinical teams
- Standards-based, flexible approach
- Remote as possible
- Private, secure
- Collaborative
- Regulatory-compliant
- Reusable
- Pluripotent

Philosophy

- Participants as part of the team; involved, engaged, respected; with agency over their data.

Solution

- Rapidly deployed, digitally enabled, participant centered platform to collect longitudinal data and facilitate observational and experimental studies.
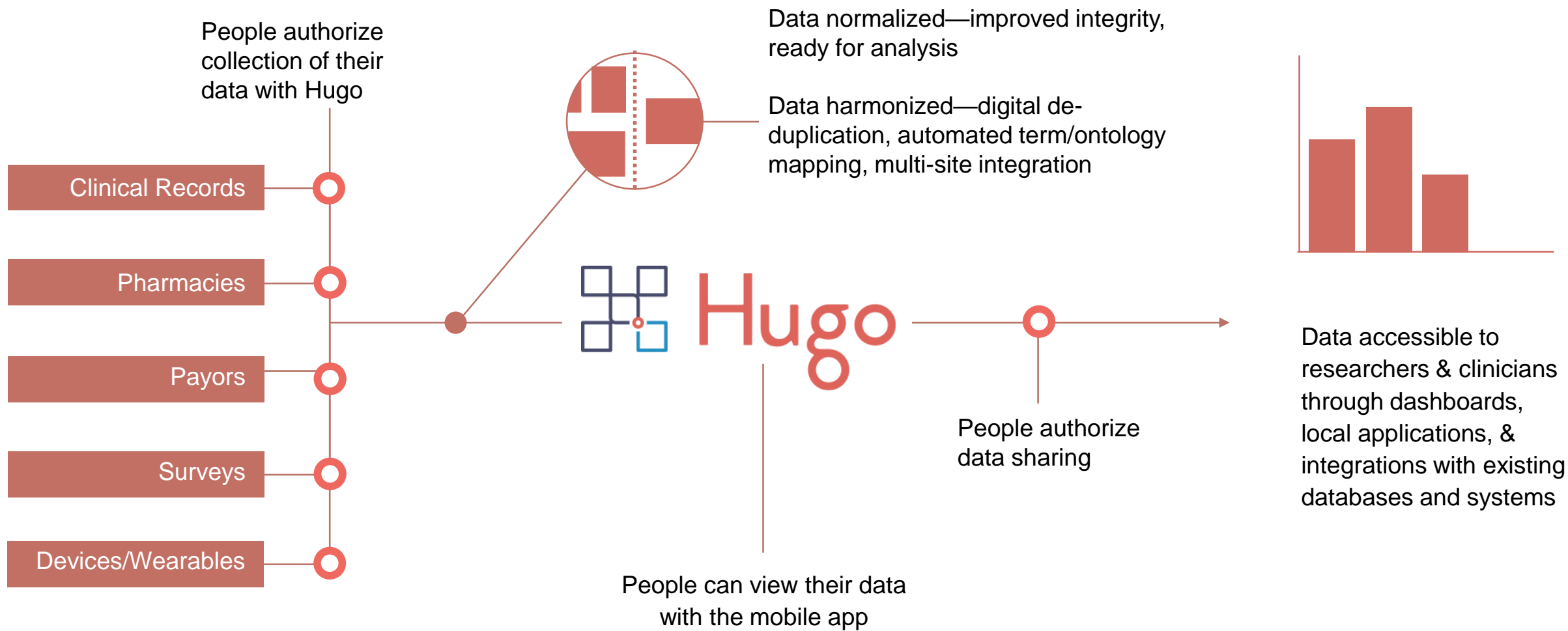
The Precision Medicine Initiative Co[...]
Program – Building a Research
Foundation for 21st Century Med[...]

Precision Medicine Initiative (PMI) Working Group Repor[...]
Advisory Committee to the Director, NIH

September 17, 2015

"... Working Group envisions an adaptation of download-and-forward capability as a "Sync for Science" application & protocol that enables participants to acquire & review their EHR data... to detect & forward clinical data as new medical events occur, full implementation of the S4S concept will require coordinated action by federal agencies..."

People authorize collection of their data with Hugo

Clinical Records

Pharmacies

Payors

Surveys

Devices/Wearables

Data normalized—improved integrity, ready for analysis

Data harmonized—digital de-duplication, automated term/ontology mapping, multi-site integration

Hugo

People can view their data with the mobile app

People authorize data sharing

Data accessible to researchers & clinicians through dashboards, local applications, & integrations with existing databases and systems

Aggregating Multiple Real-World Data Sources using a Patient-Centered Health Data Sharing Platform: an 8-week Cohort Study among Patients Undergoing Bariatric Surgery or Catheter Ablation of Atrial Fibrillation

Sanket S. Dhruva[1], Joseph S. Ross[2,3,4], Joseph G. Akar[2,5], Brittany Caldwell[6], Karla Childers[7], Wing Chow[7], Laura Ciaccio[4], Paul Coplan[7], Jun Dong[6], Hayley J. Dykhoff[8], Stephen Johnston[7], Todd Kellogg[9], Cynthia Long[6], Peter A. Noseworthy[10,11], Kurt Roberts[12], Anindita Saha[6], Andrew Yoo[7], Nilay D. Shah[8,11]

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Fig. 9
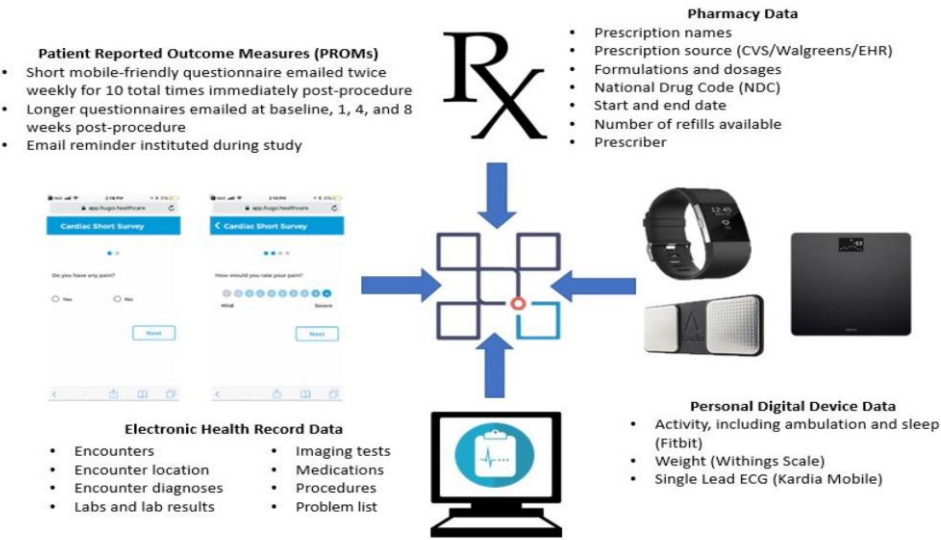
Full Title: Use of mobile health apps in low-income populations: a prospective study of

facilitators and barriers

Short Title: Liu; Use of mHealth apps in low-income populations

Patrick Liu BA[1]; Katia Astudillo BS[2]; Damaris Velez BA[2]; Lauren Kelley MSW MPA[2]; Darcey
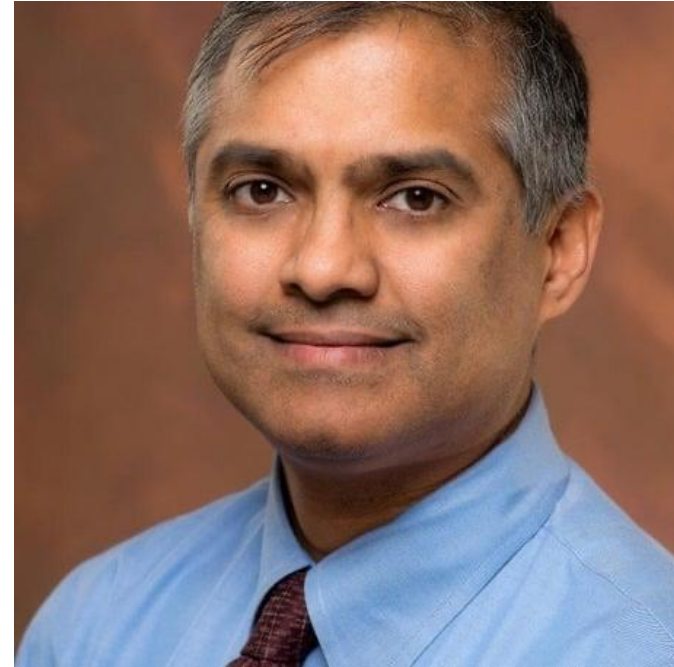
Cobbs-Lomax MBA MPH[2]; Erica S. Spatz MD MHS[3]

[1] Yale School of Medicine, New Haven, CT, 06510

[2] Project Access, New Haven, CT 06533

[3] Section of Cardiovascular Medicine, Department of Internal Medicine, Yale School of

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Haven, CT

Approach
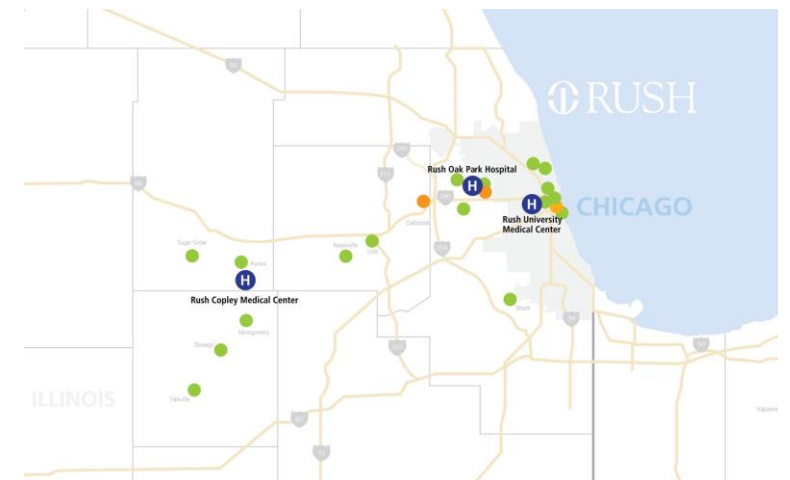
- Prototype site
- Scaling strategy

Bala Hota, MD

Rush University Medical Center

- 669 bed academic medical center
- 35,000 admissions per year
- 65,000 ED visits per year
- **Clinical Staff**
- ~1400 professional nursing staff
- ~800 attending physicians
- ~650 residents and fellows
- **Ambulatory Practices**
 - ~50 owned practices and ~100 private practices
- **Epic 2018 EHR**

Timeline

-March 2: Hospital Incident Command Established
-March 4: First COVID + Patient seen at Rush
-March 6: Rush Research Teams Activated
-March 9: Registry Protocol submitted to IRB
-March 13: Protocol Approved
-March 19: Biorepository Protocol Approved
-March 23: Hospital Surge Plan Activated
-March 27: Enrollment Begins
-March 28: Surge Begins

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Patient Characteristics

Patient Characteristics -Rush	Overall	Admitted	ICU	Vent
Total Known Covid-19 + Patients	466	111	52	33
Male	50%	59%	71%	67%
Mean Age, yr	48	57	58	58
Race				
African American	50%	56.%	48%	42%
White	25%	16%	19%	18%
Asian	3%	0%	0%	0%
Other	22%	27%	33%	39%
Hispanic Ethnicity	16%	24%	23%	36%

To date: 1159 PUIs; 466 COVID+; 111 admitted

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Enrollment Workflow

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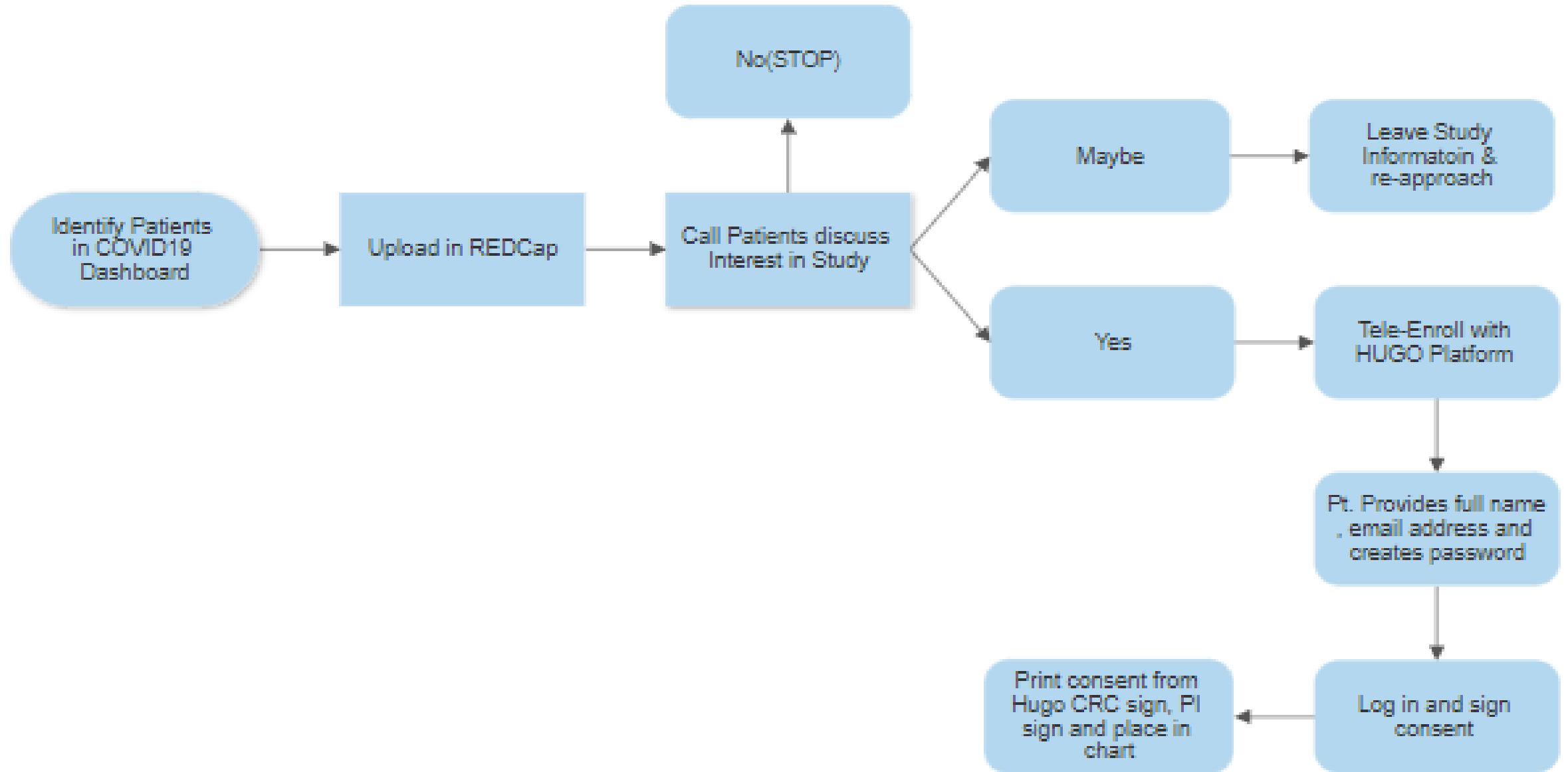
RUSH

Rush University Medical Center is hoping you will join us in our effort to better understand the experience of people with COVID-19 symptoms. We are working as fast as we can to improve outcomes for everyone by learning as much as we can from each person who is under our care. Your contribution will make a difference.

I'D LIKE TO PARTICIPATE

To participate, we ask that you use the button above to create an account with Hugo Health, the company we choose to enable you to collect your health data and share it with our research team. Hugo was created to empower people with their health data and does not do anything with your data without your permission - details are available in their Privacy Center. Hugo will allow you to link your health system and pharmacy data and receive study related surveys by email or text. Your Hugo Health account will be yours to keep and use indefinitely and free of charge.

Learn Faster. Act Quicker. Save More Lives.

RUSH

Real-World Data & Evidence in Real Time Enable Actionable Insights to Combat COVID-19

COVID-19
GLOBAL PANDEMIC
- Caused by a *novel* coronavirus
- Population devastation
- Overwhelmed health care capacity
- Economic distress

URGENT NEED FOR
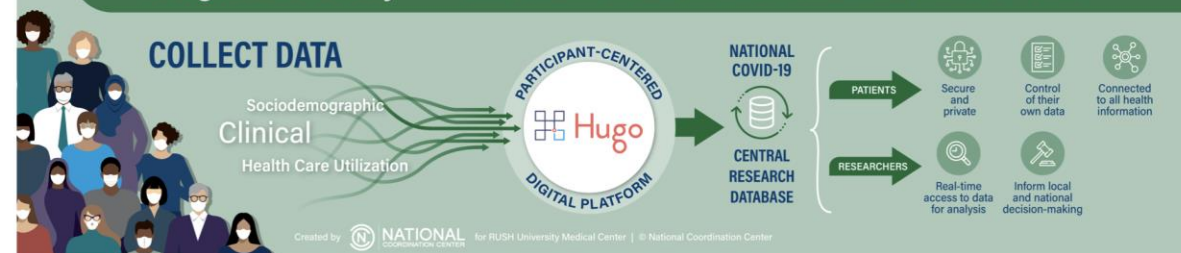KNOWLEDGE & DATA

Leverage Lessons Learned → INFORM → Better Practice & Policy

We need **platforms of knowledge generation** that produce the actionable insights that strengthen efforts to **prevent spread, mitigate impact**, and, ultimately, **save lives**.

DIGITAL-ENABLED Longitudinal Study
- Provide real-world data for real-world evidence in near real time to help fight the pandemic.
- Develop a **national digital registry** for **people under investigation (PUI)** for COVID-19.

COLLECT DATA

Sociodemographic
Clinical
Health Care Utilization

→ PARTICIPANT-CENTERED Hugo DIGITAL PLATFORM → NATIONAL COVID-19 CENTRAL RESEARCH DATABASE

PATIENTS
- Secure and private
- Control of their own data
- Connected to all health information

RESEARCHERS
- Real-time access to data for analysis
- Inform local and national decision-making

Created by NATIONAL COORDINATION CENTER for RUSH University Medical Center | © National Coordination Center

Interoperability for Scalable Registries

- Standards-based acquisition and data transfer
  - FHIR
  - CCDA
- Portal based authentication
  - OAUTH2
  - Credentials Based
- Minimal IS implementation time

Recruitment Best Practices

- Provider Engagement – include attending physician staff

- Electronic consent provides optimal workflow

- Initial consent workflow technically feasible using telephone

- Remote consent is possible

RUSH

Graham Nichol, MD

Catchment Population > 20 M

>1 M Emergency Department Visits

>2 M Outpatient Visits

Additional Locations, Sites Based
on Interest and Funding

Discussion

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